Exhibit 7

State of California ex. rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.

Exhibit to the Declaration of Steven U. Ross in Support of Plaintiffs' Opposition to Sandoz, Inc.'s Motion for Summary Judgment

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL : MDL NO. 1456

INDUSTRY AVERAGE WHOLESALE : Master File

PRICE LITIGATION : 01-CV-12257-PBS

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THIS DOCUMENT RELATES TO :

State of California, ex rel. : Judge Patti Saris

Ven-a-Care v. Abbott :

Laboratories, Inc., et al. :

Case No. 03-cv-11226-PBS :

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(CROSS NOTICED CAPTIONS ON FOLLOWING PAGES)

Videotaped deposition of THE GENERIC PHARMACEUTICAL ASSOCIATION by SHAWN M. BROWN, ESQ.

Washington, D.C.

Tuesday, February 10, 2009

9:15 a.m.

reflect that there have been several iterations of conversations and letters between us at which to some degree you narrowed the topics in this. I don't think it needs to divert us now, but I just thought I'd state that for the record.

MR. ROSS: All right. If it becomes a problem, let me know.

MR. ARAGON: Very good.

(Exhibit GPhA 053 was marked for identification.)

BY MR. ROSS:

Q. Mr. Brown, you've been handed what we've marked as Exhibit 53 to today's deposition. It's a multipage document. It's not Bates stamped, but it starts with a letter dated May 31, 2007 from the firm of Lehman, Kelly, Sadler & O'Keefe to Kevin Gorospe, G-O-R-O-S-P-E, chief of the pharmacy policy unit at California Department of Health Services. Do you see that?

A. Yes.

Q. Okay. Have you seen, before today, any part of this exhibit?

A. Yes. I looked at it in preparation for this deposition.

Q. Okay. The entire document?

A. It was in a different order when I looked at it, but I think it's all the pages I looked at.

Q. Okay. Did you speak to anybody at GPhA specifically about Exhibit 53 prior to today?

MR. ARAGON: Objection. Vague.

BY MR. ROSS:

Q. You can answer the question.

A. I asked Kathleen what she knew about lobbying efforts in California.

Q. Okay.

A. And I talked to John Benton as well, and Vince Suneja, but not specifically about this document.

Q. Okay. I'd like to direct your attention to, I believe it's the 11th page in, it's the page on GPhA letterhead that's titled, average manufacturer price. Do you see that?

A. Yes.

Q. Have you read this paper?
A. Yes.
Q. These seven pages prior to today?
A. Yes.
Q. And you're familiar with this document?
A. Yes.
Q. What would GPhA call this document?
A. A white paper.
Q. White paper. Okay. Do you know who at GPhA prepared this white paper?
A. This was prepared by outside counsel. I think we had Alston Bird draft this document.
Q. Okay. And what was the purpose for having Alston Bird draft in GPhA white paper?
A. This was to explain why AMP was not an adequate basis to calculate pharmacy reimbursement on, and to talk about the limitations of AMP and the concerns about confidentiality.
Q. Okay. Was GPhA asked by anyone to have this document prepared?
A. I'm sure our members wanted us to take some action in California.

Q. Okay. Was this white paper reviewed by the members of GPhA prior to it being sent to California?

A. Yes.

Q. Was it reviewed by or sent to all members of GPhA or just some?

A. Just some.

Q. And do you happen to know which members this white paper was sent to, and prior to its being sent to California?

A. Well, because it relates to California, I'm thinking it was sent to the state government affairs committee.

Q. And at the time, that is approximately May of 2007, which GPhA members would have been on the state government affairs committee?

A. At least Teva, Barr, Mylan, Sandoz and Watson. There are more members, too, but I couldn't tell you exactly who.

Q. What was the business of the state affairs committee?

A. Dealing with any state legislative issue

THE WITNESS: I think this document sets out some of our concerns, but I -- I don't think it sets out our entire position on AMP or pharmacy reimbursement.

BY MR. ROSS:

Q. Okay. Well, does this document -- according to you, does this document set out any position, any of GPhA's positions on the usefulness of AMPs as a basis -- excuse me, as the basis for pharmacy reimbursement?

A. Yes.

Q. Can you tell me what that position or those positions are? Can you point to a spot in the document that sets forth those positions?

A. Well, in this II, it talks about the fluctuations of AMP, and why it would be an unreliable data point to try to calculate pharmacy reimbursement on. There is a discussion in the third Roman numeral of confidentiality, and why that's important. Further on, why that would -- why disclosure of AMP -- why the disclosure of manufacturer-specific AMP would be harmful

competition in the generic industry.

And there is several other reasons why, for instance, confusion among purchasers and payers. And then the last part of the document discusses alternatives to AMP.

Q. Do you know the source or the sources of information used to put this white paper together?

MR. ARAGON: And Mr. Ross, one second please. Because this was drafted by outside counsel and to some degree there is a privilege, I'm going to ask the witness not to discuss things that he knows occurred in a privilege context, but only this completed document, okay?

MR. ROSS: That's fine. I would never ask a question that would seek to elicit --

MR. ARAGON: We agree on everything. This is great. Okay.

THE WITNESS: The sources of this information?

BY MR. ROSS:

Q. Yes. Do you know what sources of information, what information was used to put

together or prepare this white paper?

A. I can look at the footnotes. I mean, I don't know what the law firm used to put this together.

Q. Well, did GPhA provide the law firm with any background or source information from which to put this paper together?

A. Not that I know of.

Q. Do you know whether the law firm used documents that were previously prepared by GPhA as a source of information for this white paper?

A. I don't know.

Q. Okay. If you take a look with me at the bottom of the first page of this document, under II, limitations on the usefulness of AMP. Do you see that?

A. Yes.

Q. The paragraph begins, often AMP is mistakenly perceived as an indicator of market prices. Can you tell me, Mr. Brown, what market prices this white paper is referring to?

A. Well, in other words, AMP isn't giving

you what a consumer pays for the product.

Q. Is it the price that a retail pharmacy pays for the product?

MR. ARAGON: Objection. Vague.

MR. MERKL: Objection to form.

BY MR. ROSS:

Q. You can answer the question.

A. Is AMP the price paid by the pharmacy?

Q. No. I'm asking you, looking at this first sentence here, the one that says, often AMP is mistakenly perceived as an indicator of market prices, I'm trying to get an idea in more detail, if you can give me, of what GPhA meant by market prices.

A. Well, there is some discussion in other documents about a widely available market price which would be representative of a larger portion of the market on that particular product.

Q. Yes, but would it be a price that a retail pharmacy, for example, could purchase the product at, or would it be the price that a wholesaler could purchase the product at, or a

price that the wholesaler sells the product at?

A. I'm not sure. I mean, I can tell you what AMP means in this document.

Q. Okay. What does AMP mean to you in terms of this document?

A. The average price paid to a manufacturer for products distributed in the retail pharmacy class of trade.

Q. Okay. The paragraph that we were just looking at goes on to read, however, it -- meaning AMP -- bears little relevance to market price. Do you see that?

A. No. Where is it?

Q. The bottom of the first page.

A. Okay.

Q. Okay. Is that a position that is taken by all of GPhA's members?

MR. ARAGON: Objection. Object to the form.

THE WITNESS: I don't know.

MS. LEVY: Objection to the form.

BY MR. ROSS:

Q. Well, do you know as of the time that this white paper was prepared, at some time in the spring, it looks like, of 2007, which of GPhA's members agreed with that statement?

A. I don't know.

Q. Would you agree with me that the members at the time of the state government affairs committee would have agreed with that statement?

MS. LEVY: Objection.

MR. ARAGON: Objection to form.

THE WITNESS: I think this represents a document that was representative of the industry view.

BY MR. ROSS:

Q. As opposed to GPhA's members' views?

A. As opposed to individual members' views.

Q. Okay. Well, are you aware as of 2007, at the time this white paper was prepared, of any of GPhA's members that disagreed with that position?

A. That disagreed with that position?

Q. Disagreed.

A. I'm not aware of anyone who disagreed with this position.

Q. Well, is GPhA, to your knowledge, aware of any member who disagreed with that position at this time?

MR. MERKL: Objection to form.

THE WITNESS: The position that AMP is mistakenly perceived as an indicator of market prices?

BY MR. ROSS:

Q. Yes. And that it bears little relevance to market price?

A. I don't know of any member company who disagrees with that.

Q. Have you seen anything in any document that you've reviewed in preparation for this deposition that would indicate to you that any member company disagreed with that position?

A. No.

Q. So is it GPhA's position or opinion that as of May 2007, that if California, for example, wanted to find out what a retail pharmacy paid for

a certain manufacturer's product, that it would be mistaken -- that the state would be mistaken to use AMP to try to find out the answer to that question?

MS. LEVY: Objection.

MR. ARAGON: Objection to the form.

THE WITNESS: I think if California was trying to get the price charged to consumers, that using AMP would not be an accurate way of calculating that.

BY MR. ROSS:

Q. Okay. And is it GPhA's opinion that as of May 2007, its members would agree with that?

MR. ARAGON: Objection. Foundation.

THE WITNESS: Would agree with what I just said?

BY MR. ROSS:

Q. Yes.

A. I think they would.

(Exhibit GPhA 054 was marked for identification.)

BY MR. ROSS:

A. GPhA will put together task forces to address particular issues. And then whatever member companies want to participate, they will join into discussions that usually occur regularly either every week or every month. And that's where you discuss whatever issue it is, and try to get a consensus position or decide on what actions the association should take.

Q. Can you tell me what the purpose of the AMP task force was?

A. To address our concern, the industry's concerns about AMP.

Q. Okay. Is the AMP task force still around?

A. I don't think so. It's either dormant or gone.

Q. Do you know when it was created?

A. I think it was created -- I think it was called originally the Medicaid task force, and it started in 2005 in response to the Deficit Reduction Act, the federal legislation.

Q. Okay. So if I mention Medicaid task

force or AMP task force, I'm talking about the same thing?

A. I think so.

Q. As of May 2007, can you list for me the members of the AMP or Medicaid task force?

A. I think we have a list.

Q. Can you just off the top of your head right now, can you name for me any of the member companies?

A. Yes. Teva, Barr, Sandoz, Mylan, Watson, and there were certainly other members.

Q. Was there any GPhA employee that was also a member of that task force?

A. Yes.

Q. And who would that have been?

A. Bruce Lott. I think I'm on there, and I think Kathleen is on there. A lot of the people who were on that list really only signed up to get the emails, and they don't necessarily participate in the discussions.

Q. Okay. Did GPhA receive any response from any of the board of directors or AMP task

Q. Okay. Was the analysis that's mentioned in Miss Cottrell's email ever prepared by LECG?

A. To my knowledge, it was never prepared.

Q. Okay. And do you know why it was never prepared?

A. Because they didn't get enough information.

Q. And that was told to you by Mr. Kahwaty?

A. LECG.

Q. LECG. Okay.

A. Told the GPhA.

Q. Okay. So as far as GPhA is concerned, that LECG analysis was never prepared, correct?

A. That's right.

(Exhibit GPhA 057 was marked for identification.)

BY MR. ROSS:

Q. You've just been handed what we've marked as Exhibit 57. It's a one-page letter dated October 25, 2005 on GPhA letterhead from Kathleen Jaeger to Charles Grassley, Chairman, Committee on Finance and Max Baucus, Ranking

Member, Committee on Finance. Do you see that?

A. Yes.

Q. Okay. For the record, I believe we pulled this letter off of the GPhA website. So there is no Bates number on this. Are you familiar with this letter?

A. Yes.

Q. Is this one of the documents that you reviewed in preparation for today's deposition?

A. Yes.

Q. What was the purpose of Miss Jaeger sending this letter?

A. I think we wanted to caution them from using AMP as a basis to calculate pharmacy reimbursement.

Q. Caution the United States Senate Committee on Finance, is that what you're referring to?

A. Right. Yes.

Q. Okay. And as expressed to the committee, what were the problems or what was the problem of using AMP as a basis for pharmacy

reimbursement?

MR. ARAGON: Objection. Document speaks for itself.

THE WITNESS: I mean, they are the same thing as expressed in the document, that it would drive some pharmacies out of the Medicaid program. They didn't think it was -- would be an accurate reflection of true market prices, that AMP would be.

BY MR. ROSS:

Q. Okay. So GPhA in this letter, this Exhibit 57, is taking the same position or expressing the same opinion to the United States Senate as it did later on to California? Is that correct?

A. That AMP is not a sufficient means of calculating pharmacy reimbursement. Yes.

Q. Okay. Was this letter, Exhibit 57, circulated to any of the GPhA membership prior to Miss Jaeger sending it to Congress?

A. Yes.

Q. As far as you're aware, did any GPhA

member object to any of the language set forth in Exhibit 57 prior to it being sent to Congress?

A. Not that I know of.

Q. And you saw nothing in your review of the documents, the GPhA documents that would lead you to believe that any GPhA member objected to anything in Exhibit 57?

A. Right.

Q. Correct?

A. Right. Correct.

Q. Okay. Thank you.

(Exhibit GPhA 058 was marked for identification.)

BY MR. ROSS: It.

Q. Mr. Brown, you've been handed what we've marked as Exhibit 58, which is a multi-paged letter, 18 page letter, Bates stamped GPhA-CA 00866 through 883 dated February 20, 2007 signed by -- apparently by Miss Jaeger for delivery to Centers for Medicare & Medicaid Services. Do you see that?

A. Yes.

Q. Okay. Are you familiar with Exhibit 58?
A. Yes.
Q. Is this one of the documents that you reviewed in preparation for today's deposition?
A. Yes.
Q. What was the purpose of Miss Jaeger sending Exhibit 58 to CMS?
A. They were requesting comments on implementing regulations, and so these were the views of our association.
Q. Okay. Was Exhibit 58 circulated to GPhA's members prior to it being sent to CMS?
A. Yes.
Q. Okay. And as far as you're aware, did any member have any objection to any of the portion of the letter as actually sent to CMS?
A. No. Not as far as I'm aware.
Q. Okay. If you take a look with me at the second page, the second full paragraph.
A. Not only are AMP?
Q. Yes. I'll read that into the record. Not only are AMP calculations skewed by this lack

of data but they are also easily misinterpreted. This misinterpretation occurs when payers, state agencies and consumers, rely on AMPs to indicate actual prices available in the marketplace. That is the position consistently taken by GPhA regarding the relevancy of AMPs to market prices, correct?

A. Correct.

Q. Okay. And this is the same position that GPhA expressed to California in 2007, correct?

MR. ARAGON: Objection. Foundation.

THE WITNESS: I mean, I don't know exactly how it was phrased in the document, but in general, that's right.

BY MR. ROSS:

Q. Okay.

(Exhibit GPhA 059 was marked for identification.)

BY MR. ROSS:

Q. All right. Mr. Brown, you've been handed what we've marked as Exhibit 59. Looks

A. Right.

Q. And that time frame was 2007. Would that -- would your answer be the same for the entire period from 2005 through 2007?

A. Well, I think that when California was considering using AMP, that was when GPhA developed a response, policy response to that.

Q. Well, I understand that, but I mean, just as far as GPhA's opinion is concerned, if California wanted in 2005 to find out what a retail pharmacy paid for a particular product, could it have looked at --

A. AMP would not have been a good indicator.

Q. Thank you very much. I don't have any further questions. I'm going to pass the mic.

MR. ARAGON: It may be better, it doesn't matter to me, before we move on, I think there may be some follow-up questions, Mr. Ross, to the questions you asked. Maybe we should throw the floor open.

MR. CHRISTOFFERSON: That's correct.

LEHMAN·KELLY·SADLER & O'KEEFE

May 31, 2007

Richard LEHMAN
Anne KELLY
Scott SADLER
Erin O'KEEFE

J. Kevin Gorospe, Pharm. D.
Chief, Pharmacy Policy Unit
California Department of Health Services
Medi-Cal Policy Division
1501 Capitol Avenue, Suite 71.3041, MS 4604
Sacramento, CA 95814-7417

Dear Kevin,

Thank you for meeting with our client, Mylan Laboratories, Inc. recently to discuss the proposed amendment concerning the use of average manufacturers price ("AMP") for Medi-Cal reimbursement. After our meeting, we reached out to other members in the generic pharmaceutical industry in order to provide a more uniform proposal for your consideration.

To that end, attached to this letter you will find several documents that we have prepared in conjunction with other generic manufacturers that we hope will be of use to you in the continued development of this drug pricing policy. Specifically, attached you will find: (1) a background document describing AMP, along with a couple of alternatives to AMP that you may wish to consider; (2) a redline of the proposed amendment reflecting several conceptual changes for your consideration; and (3) a chart providing further explanation of the changes in the amendment.

Once again, thank you for meeting with us and our client Mylan Laboratories Inc. to discuss this important policy. If Mylan Laboratories, Inc. can provide any additional information to you or your staff, please do not hesitate to let me know.

Sincerely,

Erin I. O'Keefe
Partner

EXHIBIT
Brown 53
2/10/09 SLC

GPhA
GENERIC PHARMACEUTICAL ASSOCIATION

Explanation for Suggested Changes
to the
Proposed Amendment on the Use of AMP for Medi-Cal Reimbursement

The chart below provides a brief explanation of the changes we have suggested to the proposed amendment concerning the use of AMP for Medi-Cal reimbursement. The changes we have recommended are intended to be conceptual in nature. All changes are to Section 14105.45 of the Welfare and Institutions Code.

Affected Subsection	***Rationale for Suggested Change***
Section 14105.45(a)(1)	***Net Unit Reporting*** - We believe manufacturers should be required to report net units shipped so the department has some assistance in determining if a product is widely available. (Net units shipped will also enable the department to calculate industry-wide, weighted average AMPs in the event that the department chooses to reimburse based on weighted average AMPs rather than on manufacturer-specific AMPs, as we have suggested in our White Paper.) ***Direct Price*** – Since manufacturers report AMP to the department, we do not believe there is a need for an alternative and so would recommend eliminating the sentence about direct price.
Section 14105.45(a)(3)	Per the note above, we do not believe there is a need to use direct price at any time and so have deleted this definition.
Section 14105.45(a)(4)	We have revised the definition of estimated acquisition cost to reference the provision describing how this term is calculated.
Section 14105.45(a)(6)	We have modified this definition to specifically include "authorized generics" (i.e., those instances when an innovator company, in the face of pending generic competition, repackages its own product and markets it as a "generic". Such product competes at a generic price).
Section 14105.45(a)(8)	We have revised this definition to reference the formula for determining MAIC which is described later in the statute. Given the proposed change to the definition of "generically equivalent drugs", MAIC would also include authorized generics.
Section 14105.45(a)(11)	***Ability to Mark-Up*** – We strongly agree with the current language which allows the department to mark-up the selling price as necessary to maintain beneficiary access to prescription drugs. Allowing the department that flexibility is potentially critical to access. ***Confidentiality*** - We believe the selling price should be kept confidential and not subject to disclosure. Disclosure of the selling price could lead to less competition and greater uniformity in prices. It is not that companies will act improperly, but that with greater public information, prices will just naturally tend to stabilize as manufacturers react rationally to the information available. This reduction in competition could ultimately affect access. We do not believe

Affected Subsection	*Rationale for Suggested Change*
	the Deficit Reduction Act requires public disclosure of manufacturer-specific AMP and, given the adverse consequences that could flow from such disclosure, we strongly recommend the department maintain the confidentiality of AMP data.
Section 14105.45(b)(2)(A) & Section 14105.45(b)(2)(B)	For consistency purposes, single source drugs should be the subject of (A) while innovator and noninnovator multiple source drugs should be in (B).
Section 14105.45(b)(3)(C)	***Transition Period*** – We recommend allowing a transition period (such as 270 days) so that manufacturers have sufficient time to become compliant with the reporting requirements. This transition period would help to ensure that data were not used for reimbursement until they were likely to be accurate and consistent across manufacturers. Our recommendation of 270 days is based on the combination of a: (1) 180-day compliance period during which manufacturers can digest and implement the new requirements; with (2) 90-day testing period – following the 180-day compliance period – during which AMP information may be used for research and verification purposes only. The length of the transition period can be adjusted, but we strongly encourage some meaningful amount of time that enables all manufacturers to implement the new requirements. ***Implementation Date*** – The transition period should not begin until the later of: (1) the date CMS issues its final rule on AMP; or (2) the date the department issues its regulations implementing section 14105.45. The regulations from CMS and the department are essential to understanding the requirements that manufacturers must adhere to in implementing this section.
Section 14105.45(d)	The department should issue regulations implementing the statutory requirements of Section 14105.45 to provide greater clarity and ensure consistent treatment across manufacturers. Final regulations should be issued only after a full rule-making process (including a notice and comment period) so that all interested stakeholders have an opportunity to participate in such process.

Suggested Changes to Current Legislative Proposal[1]

SEC. 47. Section 14105.45 of the Welfare and Institutions Code is amended to read:

14105.45. (a) For purposes of this section, the following definitions shall apply:

(1) "Average manufacturers price" means the price reported to the department by manufacturers which is calculated by manufacturers in a manner consistent with: (1) the requirements of Section 1927 of the Social Security Act (42 U.S.C. Sec. 1396r-8); and (2) the final regulations issued by the Centers for Medicare and Medicaid Services implementing such section of the Social Security Act. Manufacturers shall report to the department net units shipped for each product to assist the department in determining if such product is widely available. The department shall not disclose any data provided by manufacturers pursuant to this section for any purpose.

(2) "Average wholesale price" means the price for a drug product listed in the department's primary price reference source.

(4) "Estimated acquisition cost" means the price determined in accordance with the terms described in subsection (b)(2) below.

[1] Please note that these changes are intended to be conceptual in nature. To the extent the department is amenable to some or all of these changes, it may elect to implement them in a different manner on a technical basis.

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Inserted: the Centers for Medicare and Medicaid Services pursuant to Section 1927 of the Social Security Act (42 U.S.C. Sec. 1396r-8)
Deleted: In the event an average manufacturer's price is not available, the department shall use the direct price as the average manufacturer's price. ¶
Deleted: (A) The manufacturer's sales to all purchasers, excluding sales exempt under subparagraph (B), of a drug or biological in the United States in the calendar quarter, divided by the total number of the units of that drug or biological sold by the manufacturer in that calendar quarter.
Deleted: (B) In calculating the manufacturer's average sales price, the following sales shall
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Deleted: (i) Sales exempt from inclusion in the determination of "best price" under Section 1927(c)(1)(C)(i) of the Social Security Act (42 U.S.C. Sec. 1396r-8(c)(1)(C)(i)).
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(ii) Any other sales as the Secretary of the United States Department of Health and Human Services identifies as sales to an entity that are merely nominal in amount, as applied for purposes of Section 1927(c)(1)(C)(ii)(III) of the Social Security Act (42 U.S.C. Sec. 1396 ... [1]
Deleted: (C) In calculating the manufacturer's average sales price, the price shall include volume discoun ... [2]
Deleted: (D) In the case of a drug or biological during an initial period, not to exceed a full calendar quarter, in v ... [3]
Deleted: (3) "Direct price" means the price for a drug product purchased by a pharmacy directly from a drug ... [4]
Deleted: department's best estimate of the price generally and currently paid by providers for a drug product sold b ... [5]
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(5) "Federal upper limit" means the maximum per unit reimbursement when established by the Centers for Medicare and Medicaid Services and published by the department in Medi-Cal pharmacy provider bulletins and manuals.

(6) "Generically equivalent drugs" means drug products with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name, as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), as those drugs products having the same chemical ingredients. This term shall include "authorized generic drugs," which is any drug sold, licensed, or marketed under a new drug application approved by the FDA under section 505(c) of the Federal Food, Drug, and Cosmetic Act; and marketed, sold or distributed directly or indirectly under a different product code, labeler code, trade name, trade mark, or packaging (other than repackaging the listed drug for use in institutions) than the listed drug. (7) "Legend drug" means any drug whose labeling states "Caution: Federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

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(8) "Maximum allowable ingredient cost" (MAIC) means the maximum amount the department will reimburse Medi-Cal pharmacy providers for generically equivalent drugs, based on the formula described in section (b)(3) below. (Note: Pursuant to the suggested changes above under (6), for purposes of the MAIC, the term "generically equivalent drugs" would also specifically include authorized generics).

(9) "Innovator multiple source drug," "noninnovator multiple source drug," and "single source drug" have the same meaning as those terms are defined in Section 1396r-8(k)(7) of Title 42 of the United States Code.

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(10) "Nonlegend drug" means any drug whose labeling does not contain the statement referenced in paragraph (7).

Deleted: (11) "Wholesale selling price" means the weighted (by unit volume) mean price, including discounts and rebates, paid by a pharmacy to a wholesale drug distributor.

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(11) Selling price" means the price used in the establishment of the estimated acquisition cost. The department shall base the selling price on the average manufacturers price plus a percent markup determined by the department as necessary to maintain beneficiary access to prescription drug services. The selling price shall be considered confidential and shall not be subject to disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

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(b) (1) Reimbursement to Medi-Cal pharmacy providers for legend and nonlegend drugs shall consist of the estimated acquisition cost of the drug plus a professional fee for dispensing. The professional fee shall be seven dollars and twenty-five ($7.25) per dispensed prescription. The professional fee for legend drugs dispensed to a beneficiary residing in a skilled nursing facility or intermediate care facility shall be eight dollars ($8) per dispensed prescription. For purposes of this paragraph "skilled nursing facility" and "intermediate care facility" shall have the same meaning as defined in Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations.

(2) The department shall establish the estimated acquisition cost of legend and nonlegend drugs as follows:

(A) For single source drugs, the estimated acquisition cost shall be equal to the lowest of the average wholesale price minus 17 percent, the selling price, or the MAIC.

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(B) For innovator and noninnovator multiple source drugs, the estimated acquisition cost shall be equal to the lowest of the average wholesale price minus 17 percent, the selling price, the federal upper limit, or the MAIC.

Deleted: (C) The department shall not use the direct price paid by pharmacies to drug manufacturers to establish estimated acquisition cost.

(3) For purposes of paragraph (2), the department shall establish a list of MAICs for generically equivalent drugs, which shall be published in pharmacy provider bulletins and manuals. The department shall update the list of MAICs and establish additional MAICs in accordance with all of the following:

(A) The department shall base the MAIC on the mean of the average manufacturers price of drugs generically equivalent to the particular innovator drug plus a percent markup determined by the department as necessary to maintain beneficiary access to prescription drug services.

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Deleted: that are available in California from wholesale drug distributors selected by the department

Deleted: (B) The department shall notify each selected wholesale drug distributo

Deleted: , in writing, that the wholesale drug distributor has been identified as a source of wholesale selling price information.

Deleted: (C) Wholesale drug distributors notified pursuant to subparagraph (B) shall, no later than 30 days after the end of each month, and in a format determined by the department, provide to the department the wholesale selling price of all legend and nonlegend drugs sold to pharmacies.

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(B) The department shall update MAICs at least every three months and notify Medi-Cal providers at least 30 days prior to the effective date of a MAIC.

(C) The department shall begin using average manufacturers price for Medi-Cal reimbursement no sooner than 270 days after the later of: (1) the date on which the Centers for Medicare and Medicaid Services issues the final regulations implementing Section 1927 of the Social Security Act (42 U.S.C. Sec. 1396r-8); or (2) the date on which the department issues regulations implementing this section 14105.45. (Note: The recommendation of 270 days is based on the combination of a: (1) 180-day compliance

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period during which manufacturers can implement the requirements; with (2) 90-day testing period - following the 180-day compliance period - during which AMP information may be verified for compliance purposes. The length of the compliance and testing period can be adjusted, but we strongly encourage some meaningful amount of time that enables all manufacturers to implement the new requirements).

(c) The department shall update the Medi-Cal claims processing system to reflect the selling price of drugs not later than 30 days after receiving the average manufacturers price.

(d) The department shall issue regulations implementing this section. Such regulations shall be issued in final form only after a full rule-making process, including a notice and comment period. This will allow the department to obtain input from all stakeholders, including but not limited to manufacturers and pharmacies.

Deleted: (E) The failure of a wholesaler to report wholesale selling prices pursuant to subparagraph (C) of paragraph (3) of subdivision (b) shall result in the director denying payment for all drugs supplied by that wholesaler to Medi-Cal program beneficiaries. The denial of payment shall be effective no sooner than 30 days after notifying pharmacy providers of the change through a provider bulletin.¶
(F) All pricing information reported by a wholesale distributor to the department pursuant to this section shall be considered confidential and corporate proprietary information and shall not be subject to disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).¶
(e)(1) Manufacturers and principal labelers of legend and nonlegend drugs shall, no later than 30 days after the end of each calendar quarter, and in a format determined by the department, provide to the department the average sale price of each of the manufacturer's legend and nonlegend drugs.¶
(2)

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Deleted: (3) For manufacturers that fail to provide average selling price information pursuant to this section, the department may subject their drugs' availability to prior authorization. The provisions of this subdivision shall be included in contracts or contract amendments entered into by the department pursuant to Section 14105.3, 14105.33, 14105.37, or 14105.39, and manufacturers shall continue rebate payments according to the rebate provisions in the contracts. Nothing in this paragraph shall affect a Medi-Cal beneficiary's ability to receive continuity of care for 60 days as contained in subdivision (i) of Section 14105.33.¶
(4) All pricing information reporte ... [6]

Deleted: Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the

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Deleted: may take the actions specified in this section by means of a provider bulletin or notice, policy letter, or other similar instructions, without taking regulatory action.

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(ii) Any other sales as the Secretary of the United States Department of Health and Human Services identifies as sales to an entity that are merely nominal in amount, as applied for purposes of Section 1927(c)(1)(C)(ii)(III) of the Social Security Act (42 U.S.C. Sec. 1396r-8(c)(1)(C)(ii)(III)), except as the secretary may otherwise provide.

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(C) In calculating the manufacturer's average sales price, the price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates, other than rebates under Section 1927 of the Social Security Act (42 U.S.C. Sec. 1396r-8). After 2004, the secretary may include in the manufacturer's average sales price other price concessions, which may be based on recommendations of the Inspector General of the United States Department of Health and Human Services, that would result in a reduction of the cost to the purchaser.

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(D) In the case of a drug or biological during an initial period, not to exceed a full calendar quarter, in which data on the prices for sales for the drug or biological are not sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the department may determine the amount payable under this section for the drug or biological based on the wholesale selling price.

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(3) "Direct price" means the price for a drug product purchased by a pharmacy directly from a drug manufacturer listed in the department's primary reference source.

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department's best estimate of the price generally and currently paid by providers for a drug product sold by a particular manufacturer or principal labeler in a standard package.

(3) For manufacturers that fail to provide average selling price information pursuant to this section, the department may subject their drugs' availability to prior authorization. The provisions of this subdivision shall be included in contracts or contract amendments entered into by the department pursuant to Section 14105.3, 14105.33, 14105.37, or 14105.39, and manufacturers shall continue rebate payments according to the rebate provisions in the contracts. Nothing in this paragraph shall affect a Medi-Cal beneficiary's ability to receive continuity of care for 60 days as contained in subdivision (i) of Section 14105.33.

(4) All pricing information reported by manufacturers and principal labelers of legend and nonlegend drugs to the department pursuant to this section shall be considered confidential and corporate proprietary information and shall not be subject to disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code.

GPhA
GENERIC PHARMACEUTICAL ASSOCIATION

Average Manufacturer Price

During your recent meeting with Mylan regarding the proposed amendment to the Medi-Cal reimbursement methodology, they mentioned that there are pricing benchmarks other than average manufacturers price ("AMP") that should be considered. We would like to take this opportunity to provide you with more information concerning some of these alternative benchmarks. To set the stage for the discussion of these alternatives, we are also providing you with some background information on the nature of AMP data, including limitations on the usefulness of these data and the dangers associated with disclosure of AMPs. In light of these concerns, we illustrate the potential advantages of the alternative pricing points over manufacturer-specific AMPs.

If you have any questions relating to this paper or if there is any additional information we can provide, please do not hesitate to let us know.

I. Introduction to Average Manufacturer Price

Under the Social Security Act, as modified by the Deficit Reduction Act ("DRA"), AMP is defined as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade."[1] Also pursuant to DRA amendments, the Social Security Act now requires the Centers for Medicare and Medicaid Services ("CMS") to report AMPs to states on a monthly basis and to post these data on a website at least quarterly.[2]

In December 2006, CMS issued a proposed rule implementing the relevant provisions of the DRA (the "Proposed Rule").[3] The Proposed Rule further specifies how manufacturers should calculate AMPs for their statutorily-required AMP submissions to the agency and, in addition, how the agency will complete its own AMP reports to the states. As AMP data becomes available to states (and, in some form, to the public), it is imperative that policymakers understand the true meaning of such data. As will be discussed more fully below, rather than reflecting actual prices available in the marketplace, AMP represents only a snapshot in time of a complex set of sales records. In addition, AMPs may frequently be lower than the prices widely available to purchasers.

II. Limitations on the Usefulness of AMP

Often, AMP is mistakenly perceived as an indicator of market prices. However, it bears little relevance to market price. A variety of normal business activities cause

[1] Social Security Act § 1927(k)(1).
[2] Social Security Act § 1927(b)(3).
[3] 71 *Fed. Reg.* 77174 (December 22, 2006). CMS has not yet issued the final rule relating to AMP but is expected to do so within the next several months.

periodic deflations or inflations of AMP from month-to-month. Some such activities include reduced sales of a product due to: backorders; temporary discontinuation of a product; or low demand from a manufacturer's current customer base. Fluctuations also occur in ordinary sales where there are timing differentials between the particular sales and the application of the associated customer credits, and swings in sales and credits that make AMPs particularly unreliable during the first few months of a product launch.

The best illustration of AMP's failure to portray market prices is the fact that during the ordinary distribution of a product, it can have three different price points, each of which could impact its AMP. These three prices are the following: (1) the price the wholesaler pays to the manufacturer, (2) the price the customer pays to the wholesaler, and (3) the price ultimately experienced by the manufacturer after chargebacks and other discounts in the ordinary course of business are taken into account. Because these different prices appear for each product within its ordinary distribution and could affect AMP, by the time AMP gets reported, the price is already outdated.

Moreover, there are a variety of discounts and other transactions that commonly occur in the prescription drug market which cause AMPs to fluctuate regularly, and sometimes significantly, in the ordinary course of business. One particular type of transaction producing such a timing differential is a sale with a market share rebate. Market share rebates are always processed on a lag because the manufacturer needs to obtain customer data reflecting the percent of prescriptions filled with product from a particular manufacturer compared with product filled from other manufacturers. The lag period can result in an additional 30 to 45 or more days until the transaction is fully closed, during which time the data are compiled by the customer and verified by the manufacturer for reasonableness.[4]

Even if smoothing is adopted in calculating AMP, the use of smoothing will not necessarily yield more accurate results. Because the erratic timing of transactions occurs within the ordinary course of business, AMPs published on the CMS website would not provide an accurate portrayal of the market. Using a "smoothing" mechanism to lag some of these transactions can help reduce some of the fluctuations in AMP (as discussed in more detail later in this letter) but cannot transform AMP into a reliable number.

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[4] Another source of timing differentials is the stocking adjustment, which is required when the manufacturer implements a price change. A stocking adjustment is processed on a lag because the manufacturer needs to obtain customer data reflecting the inventory levels for a product at a customer's distribution centers at the date the price was reduced by a manufacturer. The lag period, again, can result in 30 to 45 or more days after the applicable period after data are compiled by the customer and verified by the manufacturer for reasonableness. Stocking adjustment dollar values can be substantial depending on inventory levels at a customer and the amount of the price decrease. The impact on AMP is even greater because of the timing of the processed credit during the period when the manufacturer is billing a customer at the new price. For example, if the manufacturer had a price of $20 during January 2006 and lowered the price to $12 during February 2006, then an adjustment claim of $8 a bottle would be processed in March 2006 when the price is $12 and give the false impression via AMP of a net $4 price or less during March 2006 ($12 new price less the $8 adjustment for Jan 2006 inventory) depending on the customer inventory levels of the adjustment.

For the reasons described above, AMP bears little relevance to market price. Instead, AMP represents a price point realized by the manufacturer at a given time period based on a number of complex transactions. In addition, the intrinsic nature of AMP underscores the need to maintain the confidentiality of AMP data.

III. Need for Confidentiality of AMP Data

Due to the inherent limitations on AMP, as California determines how – if at all – to use AMP in the Medi-Cal Program, it should seek to avoid a variety of undesirable and unintended consequences that could occur with this use of such number, particularly with any disclosure of manufacturer-specific AMPs to the public. Such disclosure could result in both confusion of consumers and a convergence of market prices. Each of these outcomes has the potential to cause serious harm to the generic drug market – which has already proven its tremendous ability to achieve prescription drug cost-containment for both consumers and payers nationwide. California should bear in mind the cost-savings potential of generic drugs when making decisions on Medi-Cal reimbursement that could affect the generic market.

A. The Dangers of AMP Publication

1. Reduced Competition

Unlike single source drugs where the manufacturer has wide latitude to establish and maintain the price, many generic drugs are viewed as commodities to be purchased at the lowest possible price. While competition is usually healthy, publishing manufacturer-specific AMPs for generic drugs has the potential to do more harm than good by creating a never-ending downward price spiral. Such a dynamic could result in less competition in the marketplace as generic manufacturers may consider ceasing to offer products that are no longer profitable within these pricing dynamics.

With less competition, the end result may be higher costs for government payers for some products due to fewer generic choices. To mitigate this outcome, California should treat any manufacturer-specific AMPs it receives as confidential information. To the extent that disclosure of Medi-Cal reimbursement information is necessary, the Department should release only aggregated, industry-wide weighted average AMPs for multiple source drugs, as discussed further below.

2. Interference with Competition

Publishing manufacturer-specific AMPs, moreover, could cause significant interference with competition. As a simple matter of economics, publication of prices in such manner may lead to less competition and greater uniformity in prices. It is not that companies will act improperly, but that with greater public information, prices could just naturally tend to stabilize as manufacturers react rationally to the information available. This uniformity of price represents a reduction in competition, which would prevent

generic drugs from offering much of the cost-savings they could otherwise offer to consumers, government health care programs, and other third party payers.

3. Confusion Among Purchasers and Payers

Yet another concern regarding any publication of manufacturer-specific AMPs is the confusion that published prices would cause purchasers and payers. For a variety of reasons, many of the published prices would not be widely available and, thus, would not be accurate indicators of the market. For instance, a manufacturer that chooses to sell a product to a single entity, regardless of volume, at a discounted price may have an atypically low or high AMP. A manufacturer with a large proportion of sales to large volume purchasers at discounted prices (based on the purchase of bulk package sizes) could also have a very low AMP. Because purchasers and payers viewing these published prices would not know the reasons for the AMPs, they might mistakenly think the prices are widely available and that the prices they have paid are unreasonable in comparison.

Moreover, all the published prices – even those that are not unusually low or temporarily deflated – would represent wholesale prices and not prices to the ultimate consumers, which could include dispensing fees and wholesaler/distributor markups. Thus, even published prices that were widely available as wholesaler prices would seem low to certain purchasers, who would likely be unaware of the nature of the published prices. Month-to-month fluctuations in manufacturers' AMPs (for reasons discussed above) would also be likely to confuse customers who were unfamiliar with the many complicated transactions in pharmaceutical manufacturing and sales.

B. Recommendation on Confidentiality

In light of these competitive concerns and the confusion to consumers and payers, the Department should keep confidential any manufacturer-specific AMP data obtained from manufacturers or from CMS. Whether or not the Department decides to adopt AMP as a reimbursement benchmark for Medi-Cal, it should still refrain from disclosing these data. Even if the Department decides to use manufacturer-specific AMPs for reimbursement – as is contemplated by the current legislative proposal – the Department should limit any disclosure of AMPs to aggregated, industry-wide weighted AMPs for multiple source drugs. By doing so, the Department would help avoid the detrimental consequences discussed above.

As perhaps the first state to adopt AMP as a reimbursement benchmark and as a longtime leader in health care policy, California is in the position to influence other states' decisions regarding AMP disclosure. As a likely trend-setter, California stands to play a key role in helping preserve the cost-savings potential of a highly-competitive market for generic drugs by maintaining the confidentiality of any manufacturer-specific AMP data it receives.

With this leadership role in mind, the Department should also consider the following alternatives to manufacturer-specific AMP as a new reimbursement benchmark for Medi-Cal.

IV. Alternatives to Manufacturer-Specific AMP

In the Department's current legislative proposal, Medi-Cal reimbursement would be based on "average manufacturers price," defined as "the price reported to the department by the Centers for Medicare and Medicaid Services pursuant to Section 1927 of the Social Security Act." Provided that CMS implements this section of the Social Security Act as so indicated in the Proposed Rule, the price information received by the Department under this section will be at the manufacturer level.

However, manufacturer-specific AMPs are not the only reimbursement benchmarks available to the Department. Rather, the Department is free to select the method of reimbursement from among a variety of options. Though CMS is statutorily required to report AMPs to states, states are not similarly mandated to use these data as the basis for reimbursement. The Department could, for instance, choose to base Medi-Cal reimbursement on aggregated, industry-wide weighted average AMPs or on retail survey prices ("RSPs") – both of which would be permissible, feasible, and beneficial for the reasons outlined below.

A. Aggregated, Industry-Wide Weighted Average AMP

If the Department receives individual manufacturers' AMPs and net units shipped (excluding returns) for each product from CMS or directly from manufacturers, the Department could calculate the industry-wide, weighted average price for each drug. (Net units shipped are needed in addition to AMPs in order for the Department to compute weighted averages and to assist in determining whether products are widely available.) Having obtained this information, the Department could easily complete the weighted average calculation to determine the industry-wide average price per drug, and the Department would be free to base Medi-Cal reimbursement on those numbers.

One benefit of using the aggregated, industry-wide weighted average AMPs rather than individual manufacturers' AMPs is that the Department could disclose the industry-wide numbers without endangering manufacturers' individual, proprietary pricing information. The Department could, thus, be transparent about its prescription drug payment rates without threatening to reduce generic competition and, thereby, limit the cost-savings available through robust generic competition and utilization.

A related advantage of this alternative is that it would help promote cost-savings. As discussed in more detail above, publication of individual manufacturers' pricing information may lead to the homogenization of prices. The use of manufacturer-specific data for reimbursement purposes could have a similar effect. As prices naturally stabilize in response to the use and publication of individual manufacturers' AMPs, some generic manufacturers may be pushed out of the market. By selecting a baseline for Medi-Cal

reimbursement other than manufacturer-specific AMP, such as an aggregated, industry-wide weighted average AMP, the Department could avoid this downward pricing spiral and, thereby, help generic drugs continue to foster prescription drug cost-containment.

B. Retail Survey Price

Because states are not required to use AMP for reimbursement at all (either at the manufacturer or industry-wide level), the Department could choose to use another price point entirely. One such price point is the retail survey price ("RSP"). The Social Security Act defines "retail survey price" as, for each drug, the nationwide average of all consumer purchase prices for that drug.[5] This section of the Social Security Act permits CMS to contract with an outside vendor to conduct a monthly survey of retail prices of outpatient drugs covered under the Medicaid Program. Any data collected in such a survey must be reported to states on at least a monthly basis.[6]

Because CMS has entered a contract under these provisions, the Department can expect to begin receiving RSP data at some point in the future.[7] At that point, the Department could begin using these prices for Medi-Cal reimbursement, provided that CMS does not place any restrictions on the use of RSP data in the interim.

Using RSPs instead of manufacturer-specific AMPs would provide the same benefits discussed above in relation to the use of aggregated, industry-wide weighted average AMPs. That is, the Department could publish its Medi-Cal payment rates without either endangering sensitive proprietary information or constraining the cost-savings potential of generic drugs. In fact, using RSPs may even encourage generic utilization because RSPs may more accurately reflect pharmacies' selling prices rather than the net prices realized by the manufacturers. This would help ensure adequate pharmacy reimbursement, which is an essential precursor for ensuring that it remains economically beneficial for pharmacies to continue offering generics.

In addition, whereas the Department would need to compute aggregated, industry-wide weighted average AMPs from information obtained either from CMS or from manufacturers directly, the Department would not need to carry out any calculations to obtain RSPs. Rather, RSP data gathered by the third party contractor would be delivered to the Department in the same form in which these data could be used for reimbursement purposes. Thus, the administrative burden on the Department would be minimized.

V. Conclusion

As California stands poised to usher in a new methodology for Medicaid drug reimbursement, there are several issues to consider. First among these is the nature of

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[5] Social Security Act § 1927(f)(1)(A)(i).
[6] Social Security Act § 1927(f)(1)(E).
[7] CMS Performance Budget for FY 2008, p. 197 (February 15, 2007), *available at* http://www.cms.hhs.gov/GPRA/Downloads/FY2008CMSCJ.pdf.

AMP as a constantly fluctuating number that does not necessarily represent the widely available market price. Also central are the duties that flow from an understanding of the true nature of AMP – i.e. the commitment to neither rely on nor characterize AMPs as market indicators, and the urgent need to keep individual manufacturers' pricing information confidential.

Careful attention to these issues ultimately entails the consideration of pricing points other than manufacturer-specific AMPs as the benchmark for Medi-Cal reimbursement. By fully deliberating the issues and weighing the alternatives, California can encourage robust competition in generic drugs, which can, in turn, help lower nationwide spending on prescription drugs. As a likely exemplar for other states' adoption or rejection of AMP, California should properly gauge its role and seek to set as valuable a precedent as possible.

* * *

We appreciate the opportunity to submit this paper to you and look forward to working with you as Medi-Cal considers the best way to reimburse for drugs. If there is anything we can do to be of further assistance, please let us know.

GPhA
GENERIC PHARMACEUTICAL ASSOCIATION

GPhA Letter on Pharmacy Reimbursement

October 25, 2005

The Honorable Charles Grassley, Chairman
Committee on Finance
United States Senate
Washington, DC 20510

The Honorable Max Baucus, Ranking Member
Committee on Finance
United States Senate
Washington, DC 20510

Dear Mr. Chairman and Senator:

As the Senate Finance Committee searches for an alternative pharmacy reimbursement model, the Generic Pharmaceutical Association urges that the Committee to reject the current Average Manufacturer Price (AMP) based model as the basis for pharmacy reimbursement. However, should the Committee approve an AMP-based model, we strongly urge the Senate Finance Committee to include provision requiring CMS to conduct and complete a study at
least 6 months prior to implementation of this proposal in order to determine the impact on beneficiaries, pharmacies, generic utilization and the Medicaid program.

GPhA strongly believes that any pharmacy reimbursement model based on AMP would result in reimbursements to pharmacy that would be lower than acquisition costs. Such a reimbursement model could drive some pharmacies out of the Medicaid program or result in reducing access to pharmaceuticals for Medicaid patients.

GPhA believes that any model should be built on a reimbursement which is market-based, accurately reflects pharmacy costs, encourages generic drug utilization, and ensures fair and adequate reimbursement to pharmacists. Utilizing a market-based approach preserves the competitive nature of the generic marketplace that continues to provide affordable medicines for all consumers. We urge the Committee to consider market-based alternatives for pharmacy reimbursement.

Sincerely,

Kathleen Jaeger
President & CEO

Back

GPhA
GENERIC PHARMACEUTICAL ASSOCIATION

February 20, 2007

VIA HAND DELIVERY
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

FEB 2 0 2007

RE: Comments to the Medicaid Program; Prescription Drugs Proposed Rule [CMS-2238-P]

Dear Sir or Madam:

The Generic Pharmaceutical Association ("GPhA") is pleased to submit these comments on the *Medicaid Program; Prescription Drugs Proposed Rule* (the "Proposed Rule").[1] GPhA shares the commitment of the Centers for Medicare and Medicaid Services ("CMS") to implement the Medicaid Drug Rebate Program reforms mandated by the Deficit Reduction Act of 2005 ("DRA") in ways that save money for the Medicaid program, that are practicable for manufacturers, and that do not adversely impact the care furnished to Medicaid recipients. Accordingly, GPhA appreciates this opportunity to respond to CMS' requests for comments on the Proposed Rule and to address some of GPhA's own concerns about such rule.

GPhA is an association representing the manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. Together, the members of GPhA manufacture more than 90 percent of all generic pharmaceuticals dispensed in the United States.

As the primary source of generic pharmaceuticals in the country, GPhA members are committed to ensuring patient access to affordable prescription drugs. In order to ensure that this effort is not compromised, CMS should provide clear guidance and impose only operationally feasible requirements on manufacturers in connection with their calculation and submission of average manufacturer price ("AMP") and best price data. For purposes of CMS' guidance, we urge the agency to speak with sufficient clarity and specificity to ensure that manufacturers understand what is required of them. At the same time, CMS must take care to ensure that compliance with these requirements is

[1] 71 *Fed. Reg.* 77174 (Dec. 22, 2006).

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feasible for manufacturers, which necessitates that manufacturers actually have access to the information that they are required to report.

In light of these concerns, GPhA supports CMS' efforts to clarify the definitions of significant terms as well as the treatment of various types of sales and prices in manufacturer calculations. However, we do have a number of recommendations for further clarification and request guidance for treatment of certain transactions when compliance with the proposed requirements is not operationally feasible for manufacturers. This operational infeasibility arises because the regulations, as proposed, require manufacturers to make calculations using data to which they do not have access. Because a chief purpose of the Proposed Rule is to obtain uniformity and accuracy in manufacturers' AMP calculations, it is critical that manufacturers understand the requirements and have the ability to implement them. We highlight this point throughout our letter.

Not only are AMP calculations skewed by this lack of data, but they are also easily misinterpreted. This misinterpretation occurs when payers, State agencies, and consumers rely on AMPs to indicate actual prices available in the marketplace. On the contrary, AMP represents only a snapshot in time (as discussed more fully below) of a complex set of sales records. In fact, given the spectrum of variables impacting AMP, there will be a different AMP for the same sale depending on the timing of the AMP calculation.

While we acknowledge that CMS has statutory obligations concerning AMP, many of our comments stem from our recognition of the flaws inherent in AMP data and the dangers of AMP publication. Accordingly we open our comments below by discussing our concerns with public disclosure. We organize our remaining comments based on the corresponding sections in the Proposed Rule.

Requirements for Manufacturers – Section 447.510[2]

Adverse Effects of Public Disclosure of AMP on the Medicaid Program

In the Proposed Rule, CMS indicates its intention to publish not only monthly AMP data, but also quarterly AMP, on the agency's website. As CMS implements this new publication provision, we strongly recommend that multiple source AMPs be reported to States and posted on the CMS website in an aggregated, industry-wide weighted average format that combines individual manufacturer AMPs into one AMP for each drug.

The public disclosure of AMP envisioned by the DRA is a concept modeled after the disclosure of Part B average sales price ("ASP"). The DRA requires that, "the Secretary shall provide on a monthly basis to States . . . the most recently reported

[2] As mentioned above, we are only addressing public disclosure of AMP here and will address other aspects of "Requirements for Manufacturers – Section 447.510" later in this letter.

average manufacturer prices for single source drugs and for multiple source drugs and shall, on at least a quarterly basis, update the information posted on the website . . .".[3] Also, the DRA allows the Secretary to disclose "through a website accessible to the public," AMPs. However, the DRA does not provide further guidance to CMS regarding how to implement these publication provisions. Instead, the DRA leaves CMS considerable discretion concerning implementation of the public disclosure provisions.

Thus, CMS should exercise its discretion and report only the aggregated, industry-wide weighted average AMPs for multiple source drugs. Though it is unwise to make these data public at all, if CMS feels it must do so, then we recommend that the agency take into account the following important considerations when determining how to implement this publication requirement.

1. ***Limitations on the Usefulness of AMP***

AMP is mistakenly perceived as an indicator of market prices. However, it bears little relevance to market price. A variety of normal business activities cause periodic deflations or inflations of AMP from month-to-month. Some such activities include reduced sales of a product due to: backorders; temporary discontinuation of a product; or low demand from a manufacturer's current customer base. Fluctuations also occur in ordinary sales where there are timing differentials between the particular sales and the application of the associated customer credits, and swings in sales and credits that make AMPs particularly unreliable during the first few months of a product launch.

By way of example, one particular type of transaction producing such a timing differential is a sale with a market share rebate. Market share rebates are always processed on a lag because the manufacturer needs to obtain customer data reflecting the percent of prescriptions filled with product from a particular manufacturer compared with product filled from all manufacturers. The lag period can result in an additional 30 to 45 or more days until the transaction is fully closed, during which time the data are compiled by the customer and verified by the manufacturer for reasonableness.

Another source of timing differentials is the stocking adjustment, which is required when the manufacturer implements a price change. A stocking adjustment is processed on a lag because the manufacturer needs to obtain customer data reflecting the inventory levels for a product at a customer's distributor centers at the date the price was reduced by a manufacturer. The lag period, again, can result in 30 to 45 or more days after the applicable period after data are compiled by the customer and verified by the manufacturer for reasonableness. Stocking adjustment dollar values can be substantial depending on inventory levels at a customer and the amount of the price decrease. The impact on AMP is even greater because of the timing of the processed credit during the period when the manufacturer is billing a customer at the new price. For example, if the manufacturer had a price of $20 during January 2006 and lowered the price to $12 during February 2006, then an adjustment claim of $8 a bottle would be processed in March 2006 when the price is $12 and give the false impression via AMP of a net $4 price or

[3] DRA § 6001(b)(1)(B).

less during March 2006 ($12 new price less the $8 adjustment for Jan 2006 inventory) depending on the customer inventory levels of the adjustment.

As these examples indicate, AMPs fluctuate regularly and sometimes significantly in the ordinary course of business. Moreover, even aside from any of these discount-related fluctuations, each product has at least three possible prices that may be included in AMP throughout its life cycle under ordinary conditions. These three prices are the following: (1) the price the wholesaler pays to the manufacturer, (2) the price the customer pays to the wholesaler, and (3) the price ultimately experienced by the manufacturer after chargebacks and other discounts in the ordinary course of business are taken into account. Because the erratic timing of transactions occurs within the ordinary course of business, AMPs published on the CMS website would not provide an accurate portrayal of the market. Using a "smoothing" mechanism to lag some of these transactions can help reduce some of the fluctuations in AMP (as discussed in more detail later in this letter) but cannot transform AMP into a reliable number.

2. ***The Benefits of Generic Utilization***

Although the AMP changes are directed to Medicaid, the impact of those changes will be seen in other government health programs, such as Medicare. Analysts and policy makers routinely attribute the success of Medicare Part D to its emphasis on the use of generics, and they expect the importance of generic drugs in pharmaceutical cost management to grow over the next several years.

For example, on September 21, 2006, then-Administrator of CMS, Mark McClellan, MD, PhD, testified before the Senate that:

> The utilization of generic drugs has played an important role in the low costs and expected further cost reductions in the drug benefit. Due in part to increasing generic drug availability, strong competition in the prescription drug marketplace has led to slower rates of growth in overall prescription drug spending. Also, the availability of excellent coverage of generic drugs in the Part D drug benefit, as well as personalized information and support to help beneficiaries find out about how they can save using generics, have been important contributors to costs that are much lower than expected. Continuing to promote greater reliance on generics when available among Medicare beneficiaries is an important strategy to keep the new drug benefit affordable over the long term.[4]

As additional evidence, CMS itself just issued a press release acknowledging the role of generic drugs in reducing prescription drug costs for both consumers and payers nationwide.[5] In the course of implementing the switch from average wholesale price

[4] "Generic Drug Utilization in the Medicare Prescription Drug Benefit," Testimony before Senate Special Committee on Aging (Sept. 21, 2006), *available at* http://www.hhs.gov/asl/testify/t060921.html.
[5] "Generic Drug Utilization on the Rise: Consumers and Payers Benefit as More Americans Turn to Generics as One Way to Save Money and Improve their Health" (February 8, 2007), *available at* http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=2081&intNumPerPage=10&checkDate=&

("AWP") to AMP as a reimbursement benchmark, it is important that CMS not undercut the benefits that generic pharmaceuticals bring to health care cost containment by rushing to publicize generic manufacturers' most sensitive and proprietary pricing information.

3. ***The Dangers of AMP Publication***

a. ***Reduced Competition***

Unlike single source drugs where the manufacturer has wide latitude to establish and maintain the price, many generic drugs are viewed as commodities to be purchased at the lowest possible price. While competition is usually healthy, publishing manufacturer-specific AMPs for generic drugs has the potential to do more harm than good by creating a never-ending downward price spiral. Such a dynamic will result in less competition in the marketplace as generic manufacturers cease to offer products that are no longer profitable within these pricing dynamics. With less competition, the end result may be higher costs for CMS for some generic products due to fewer generic choices. Publication of only aggregated, industry-wide weighted average AMPs for multiple source drugs will mitigate against this outcome.

b. ***Anticompetitive Concerns***

Publishing manufacturer-specific AMPs, moreover, raises significant anticompetitive concerns. As GPhA observed in its June 9, 2006 letter to Dr. McClellan, publication of aggregate data such as an industry-wide average is supported by long-standing interpretations of the Sherman Act, which condemn conduct that could facilitate anticompetitive collusion among competitors. In the health care industry in particular, the federal antitrust enforcement agencies have consistently recognized the potential anticompetitive impact of the sharing of specific companies' internal price-related information.[6] GPhA is concerned that, as a simple matter of economics, publication of prices in such manner will lead to less competition and greater uniformity in prices. It is not that companies will act improperly, but that with greater public information, prices will just naturally tend to stabilize as manufacturers react rationally to the information available.

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[6] *See, e.g., In re Mich. State Med. Soc'y*, 101 F.T.C. 191, 270 (1983) ("There is ... some inherent danger in allowing any collective dialogue with third party payers on questions directly related to reimbursement amounts or policies."); *see also* Federal Trade Commission, Staff Advisory Opinion from Arthur N. Lerner, Assistant Director, to Dennis L. Dedecker, D.D.S., Secretary, Utah Society of Oral & Maxillofacial Surgeons (February 8, 1985) ("Depending upon the purpose or effect of the conduct, dissemination of price information by an organization of competitors can be found to constitute or facilitate an unlawful price agreement."); *see also* Department of Justice/ Federal Trade Commission, *Statements of Antitrust Enforcement Policy in Health Care* (August 1996).

c. ***Confusion Among Purchasers and Payers***

Yet another concern regarding publication of AMPs is the confusion that published prices would cause purchasers and payers. For a variety of reasons, as discussed above, many of the published prices would not be accurate indicators of the market. In addition, many of these prices would not be widely available. For instance, a manufacturer that chooses to sell a product to a single entity, regardless of volume, at a discounted price would have an atypically low AMP. A manufacturer with a large proportion of sales to large volume purchasers at discounted prices (based on the purchase of bulk package sizes) could also have a very low AMP. In both these cases, manufacturers may not be able to make these prices available to all purchasers.

Because purchasers and payers viewing these published prices would not know the reasons for the low AMPs, they might mistakenly think the prices are widely available and that the prices they have paid are unreasonable in comparison. Moreover, all the published prices – even those that are not unusually low or temporarily deflated – would represent wholesale prices and not prices to the ultimate consumers, which would include dispensing fees and wholesaler/distributor markup fees. Thus, even published prices that were widely available as wholesaler prices would seem low to certain purchasers, who would likely be unaware of the nature of the published prices. Month-to-month fluctuations in manufacturers' AMPs (for reasons discussed above) would also be likely to confuse customers who were unfamiliar with the many complicated transactions in pharmaceutical manufacturing and sales.

4. ***Proposed Partial Solution***

In light of these concerns, we recommend that CMS do the following:

- ***Publish only aggregated, industry-wide weighted average AMPs.*** CMS should publish only the aggregated, industry-wide weighted AMPs for multiple source drugs.

- ***Delay disclosure of AMPs until after adequate compliance period.*** CMS should not disclose AMPs until the rule is finalized and manufacturers have had sufficient time to come into compliance with its requirements. This compliance period should last at least 180 days from the time the Final Rule is issued. Given manufacturers' need for additional clarity on many key issues in the Proposed Rule (discussed herein), manufacturers will not be able to publish consistent AMP data until CMS makes the required clarifications and manufacturers have time to absorb the information and implement the required changes. Before these things happen, different manufacturers may be employing disparate assumptions to calculate their respective AMPs, which will result in variability across AMPs and prevent meaningful comparison of pricing data across manufacturers. If, however, CMS waits a sufficient amount of time after the issuance of the Final Rule to publish AMPs, then there will be at least some assurance that all

stakeholders are calculating AMP in the same way. This will, in turn, ensure that the comparison of manufacturer AMPs is a fair one.

- ***Allow a testing period for AMP data.*** As discussed later in this letter, CMS should provide for a 90-day testing period, after the 180 day compliance period, during which AMP information may be used for research and verification purposes only. CMS should indicate that AMP data may not be used for reimbursement purposes during this testing period, since manufacturers will need time to gain experience with the new system.

- ***Allow refiling of monthly AMPs.*** As highlighted later in this letter, we urge CMS to allow manufacturers to refile monthly AMPs for up to three years after initially submitted, as is currently allowed with respect to quarterly AMP data. This allowance is needed in recognition of the complexity of AMP calculations and of the timing issues surrounding the availability of the data needed in these calculations.

- ***Provide a disclaimer with any public disclosure AMP.*** On the CMS website, CMS should indicate the limitations on AMP data and advise purchasers and payers that these data may not necessarily reflect the price that is available to all consumers. Such a disclaimer could help reduce purchaser and payer confusion.

Definitions – Section 447.502

1. ***"Dispensing Fee"***

Currently, individual States determine the dispensing fees paid to pharmacies. Under the Proposed Rule, the term "dispensing fee" would be defined similarly to how it is defined under the Medicare Part D program. CMS states that, "[w]e are defining this term in order to assist States in their evaluation of factors in establishing a reasonable dispensing fee to pharmacy providers. We note that while we propose to define this term, we do not intend to mandate a specific formula or methodology which the States must use to determine the dispensing fee."[7] Thus, there is no requirement in the Proposed Rule that States must pay a fair dispensing fee that accurately reflects the actual costs associated with providing the full range of pharmacy services.

However, with the potential reduction in generic drug reimbursement that will be triggered by the switch to AMP, dispensing fees become increasingly important in ensuring that pharmacies are paid fairly for filling generic prescriptions. This will influence the extent to which pharmacies can promote generic utilization. As discussed in the previous section, generic utilization has been a key force behind the reduction in prescription drug costs for consumers and for the government. To preserve these cost-saving opportunities, CMS must keep in mind the need to incentivize generic usage over

[7] 71 *Fed Reg.* 77176.

brand usage when making changes to the Medicaid Drug Rebate Program. To ensure continued and aggressive dispensing of generic products by Medicaid, CMS should encourage States to incentivize generics through State program releases that advocate fair dispensing fees.

2. ***"Manufacturer"***

GPhA is concerned that the proposed definition of the term "manufacturer" may unintentionally affect the rebate reporting and payment obligations of some entities that do not own a particular National Drug Code ("NDC") but only produce a drug under license from another company. The proposed definition states that "manufacturer" will include any "entity that does not possess legal title to the NDC," in the case of "private labeling arrangements."[8] Under current Medicaid rebate rules, only manufacturers who legally possess the NDC report and pay rebates on those drugs.[9] Whereas the definition of "manufacturer" in the rebate statute is broad enough to cover both parties in a private labeling relationship,[10] the sample rebate agreement clarifies that the term "manufacturer" refers to "the entity holding legal title to or possession of the NDC number for the Covered Outpatient Drug."[11]

The NDC refinement in the rebate agreement is an important added directive for determining who has the rebate reporting and payment obligation for a private labeled product. We are concerned that the Proposed Rule's definition of "manufacturer" could be interpreted as an intention by CMS to change the rebate agreement's definition and to require that the party without legal title to the NDC also report and pay rebates. In that case, a manufacturer could potentially be required to report on and pay a rebate for Medicaid sales of someone else's product – an outcome that would be unjust and irrational.[12] The rebate reporting and payment obligation should be on the NDC owner/manufacturer, as it is under the current system.

We believe that CMS' purpose in the Proposed Rule was to ensure that these private label sales be included in the AMP computation – not to require that both parties report and pay rebates. Thus, to ensure the proper placement of this obligation on the NDC owner, we recommend that CMS revise the definition of "manufacturer" in the Proposed Rule to clarify that any manufacturer that has the NDC would have to report and pay rebates on the drug, while a manufacturer that does not have an NDC, but rather

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[8] 71 *Fed. Reg.* 77196.

[9] In other words, if Manufacturer A produces a drug for Manufacturer B, and B owns the NDC, then B has the rebate obligation.

[10] For purposes of the rebate statute, the relevant language is the following: "(5) MANUFACTURER.—The term "manufacturer" means any entity which is engaged in— . . . (B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products." Social Security Act § 1927(k)(5). By using the term "engaged in," this definition could encompass both the entity that owns the NDC and the entity that is under contract to produce the drug.

[11] "Rebate Agreement between the Secretary of Health and Human Services and the Manufacturer Identified in Section XI of this Agreement," *available at* http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/rebateagreement.pdf.

[12] Using the example from footnote 9, it would be unfair to require Manufacturer A to pay rebates on Manufacturer B's product.

produces a drug directly on behalf of an NDC-holder for retail sales, will not be obligated to report and pay rebates on the drug (as the NDC-holder is already reporting on and paying these rebates).

Determination of Average Manufacturer Price – Section 447.504

In response to the Proposed Rule's discussion of AMP calculation, we have several requests for clarification and recommendations to ensure that manufacturers can actually implement the requirements CMS imposes. Many of these requests and recommendations are general concerns, applicable to every aspect of the proposed calculation of AMP. For this reason, we have organized the comments below such that we present our overarching concerns first. We make other suggestions item-by-item in this section after we present the broad areas of concern.

A. ***Broad Concerns***

1. ***Calculation of AMP***

a. Need for Operational Feasibility

Our first broad concern is that the requirements for calculating AMP be operationally feasible for manufacturers. An understanding of what is operationally feasible requires familiarity with the typical distribution chain for generic drugs. This pathway works as follows: generic pharmaceutical manufacturers distribute their products directly to warehousing chain pharmacies, mail order pharmacies, various managed care entities, wholesalers and distributors (who themselves resell to non-warehousing chain pharmacies, independent pharmacies, hospitals, clinics, etc.). While manufacturers are aware of the location of their drug product after the first sale, they frequently have no way of knowing where their products end up after that first purchaser resells or redistributes the product.

One example of the many situations in which manufacturers lack access to information arises with manufacturer sales to hospitals. The Proposed Rule requires manufacturers to include sales to hospitals when the drugs are used in the outpatient setting but to exclude these sales when the drugs are used in the inpatient setting.[13] However, when a manufacturer sells to a hospital, the manufacturer will not know whether the hospital ultimately uses the drugs in the outpatient context or in the inpatient context, since purchases for all hospital needs are consolidated to obtain the best possible discount. Manufacturers, therefore, are unable to ensure that their AMP calculations include only those sales in which the drugs are ultimately used in the hospital's outpatient department.

Manufacturers also experience a lack of information on downstream sales when selling to entities including, but not limited to, wholesalers, mail order pharmacies, and

[13] 71 *Fed. Reg.* 77197.

pharmacy benefit managers ("PBMs"). The AMP data reported will be much more complete and consistent if CMS imposes requirements that are clear and operationally feasible. The agency must be careful to formulate these requirements in consideration of which information is in fact available to manufacturers. If manufacturers are required to discriminate among particular types of sales but do not have access to the information that would enable them to do so, then manufacturers will be unable to comply with the requirements through no fault of their own.

b. Need for Clarity

In addition to operational feasibility, we are also concerned about the problems related to ambiguous definitions of key concepts related to the AMP calculation. Imprecise definitions could lead to inconsistent treatment of various transactions, so we recommend that CMS clearly indicate what is meant by certain terms. In particular, we request that CMS unambiguously define the following:

- "Repackagers/relabelers";
- "Nursing home pharmacies";
- "PBMs"/"Managed care organizations" ("MCOs").

Manufacturer compliance with the new mandates for AMP calculation necessitates clear and meaningful guidance from CMS.

2. Need for Consistency with Medicaid and 340B Programs

Another issue of particular importance to GPhA is the need for consistency between the Medicaid and 340B Drug Pricing Programs. In order to have drugs be Medicaid-covered, manufacturers must also participate in the Section 340B Drug Pricing Program. Under the 340B program, manufacturers must offer drugs to certain nonfederal entities at prices that do not exceed AMP decreased by the Medicaid rebate percentage (the "340B ceiling price") as specified in the statute.[14] Participation in Medicaid, thus, requires that manufacturers submit AMPs for the Medicaid Drug Rebate Program and for the 340B Drug Pricing Program.

While AMP is used in both programs, the Proposed Rule's definition of AMP will cause AMP for Medicaid purposes to differ from AMP for 340B purposes. In its January 30, 2007 letter to pharmaceutical manufacturers, the Office of Pharmacy Affairs ("OPA") clarified the definition of AMP in 340B ceiling price calculations ("OPA letter"):

> Although the Deficit Reduction Act amended the statutory definition of Average Manufacturers Price for purposes of Medicaid by removing the deduction for customary prompt payment discounts, Section 340B(c) of the Public Health

[14] SSA § 1927(k).

> Service Act states, "Any reference in this section to a provision of the Social Security Act shall be deemed to be a reference to the provision as in effect on the date of the enactment of this section." Accordingly, manufacturers that have signed pharmaceutical pricing agreements (PPAs) must continue to calculate 340B ceiling prices so that the calculated price continues to reflect a reduction for any prompt payment discounts.[15]

Thus, while AMP is used in both the 340B and the Medicaid program, the calculation for each program will differ at least in relation to the treatment of customary prompt pay discounts.

While this difference is required by statute, other differences between the two calculations that are not statutorily mandated could be eliminated, thereby reducing manufacturers' administrative burdens. In recognition of the magnitude of these burdens, OPA stated in the letter: "We welcome comments from all parties about how to best implement the 340B Program requirements in the wake of changes in related areas impacted by the DRA. Our goal would be to minimize the burden on pharmaceutical manufacturers in submitting the required data."[16]

Operationally, the differences between the 340B and Medicaid programs will require manufacturers to move from 16 to 20 calculations annually. This move does not simply add four basic calculations to manufacturers' annual compliance requirement but, rather, requires a near-complete reprogramming of the data maintenance system for each reporting period. Because the same server cannot support hundreds of calculations per month or per quarter – as would be required to comply with both programs – manufacturers' submissions to at least one program could necessarily be delayed. Thus, the issue is not simply one of an onerous burden on manufacturers but is instead one of operational impracticability.

In accordance with the sentiment of the OPA letter, we recommend that the methodology for calculating AMP be as consistent as is statutorily possible across the Medicaid and PHS/340B programs. Calculation, maintenance, and reporting of differing AMPs for the two programs would create an undue burden for manufacturers as well as unnecessary confusion for organizations involved in the delivery of health care services. Moreover, duplicative reporting would waste time and energy within the federal programs. We ask that CMS coordinate its approach with OPA to prevent these problems.

The subsections above in this comment on AMP calculation address broad concerns that underlie all our AMP comments. Thus, while the remainder of this section addresses several specific elements of the AMP calculation, our general concerns still apply.

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[15] Jimmy Mitchell, Director of OPA, "Dear Pharmaceutical Manufacturer Letter Clarifying the Definition of Average Manufacturer Price" (January 30, 2007), *available at* http://www.hrsa.gov/opa/pharm-mfg-ltr013007.htm.

[16] *Id.*

B. *Specific Concerns on Particular Sections*

1. *Customary Prompt Pay Discounts*

The Proposed Rule states that a "customary prompt pay discount" will be defined as "any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified time."[17] There are significant uncertainties, however, in this definition. Therefore, GPhA respectfully suggests that CMS clarify what is meant by "routinely offered" and specify the criteria that manufacturers should use to determine what is "routine."

In addition, we request that CMS address whether a customary prompt pay discount could be considered a manufacturer's "routinely offered" prompt pay discount if:

- It differs across customers?
- It changes over the life cycle of a product? (e.g., the prompt pay discount offered at the introduction of the product differs from the prompt pay discount offered for the remainder of the product's life cycle.)
- It is different across products?

We ask that CMS provide guidance that would address these scenarios.

2. *State Pharmaceutical Assistance Program ("SPAP") Sales and Rebates*

CMS proposes to include all SPAP sales and rebates in AMP to the extent that these sales are made to the retail pharmacy class of trade. This proposal conflicts with the treatment required under previous CMS Manufacturer Release #68, which instructs manufacturers to distinguish between "qualified" and "unqualified" SPAPs, based on criteria listed in such release.[18] Pursuant to the release, only sales to qualified SPAPs are excluded from AMP, whereas sales to unqualified SPAPs are included in AMP. We request that CMS revisit this program release to address this inconsistency.

As an additional matter, if CMS ultimately decides to include all SPAP sales and rebates, then the agency should provide guidance regarding the method of inclusion. Specifically, CMS should specify over what ratio of sales manufacturers are to apply SPAP rebates, since the data available to manufacturers do not indicate the particular sales to which the rebates apply.

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[17] 71 *Fed. Reg.* 77196.
[18] Medicaid Drug Rebate Program Release No. 68 (April 1, 2005).

Determination of Best Price – Section 447.505

Manufacturers bear substantial administrative burdens in complying with Medicaid Drug Rebate Program requirements for data submission and retention. As mentioned above, these burdens are increased in light of the DRA's change to the definition of AMP for Medicaid purposes, since this definition now differs from the definition of AMP used in the 340B program. These burdens are also increased by new reporting and retention requirements imposed on manufacturers by the Proposed Rule. In order to reduce manufacturers' already significant administrative burdens, we recommend that CMS maintain as much consistency as possible between the treatment of underlying transactions in best price and in AMP calculations.

Authorized Generic Drugs – Section 447.506

In the Proposed Rule, CMS proposes to "require the NDA holder to include sales of the authorized generic product marketed by the secondary manufacturer or the brand manufacturer's subsidiary in its calculation of AMP and best price."[19] CMS has thus indicated that brand manufacturers' rebates must be calculated based on the sales of both the branded product and the authorized generic product. We understand that this requirement entails that generic manufacturers must provide their authorized generic drug information to the branded company holding the NDA. To avoid any potential antitrust implications that this exchange of information could raise, we request that CMS make the Federal Trade Commission ("FTC") aware of this requirement before implementing it.

Requirements for Manufacturers – Section 447.510

As noted at the beginning of these comments, the most important issue raised by the Proposed Rule for manufacturers is the public disclosure of AMP, and so we discussed this requirement at the outset rather than here with our other comments relating to this section of the Proposed Rule. Below we present the rest of our comments concerning the proposed requirements for manufacturers.

1. ***Time to Implement Operational Changes***

Complex administrative system changes and additions will be needed to implement the new definitions and reporting requirements in the Final Rule. However, the proposed effective dates do not create adequate time to design and operationalize these changes. The certification required by the Proposed Rule, and the consequences of inaccurate certification, necessitate the utmost accuracy and reliability in the reporting of manufacturers' data. The revised definition of AMP requires new data fields to be created and substantial reprogramming of sales reporting systems that must be tested and validated. Manufacturers must also ensure that their government-pricing calculation is

[19] 71 *Fed. Reg.* 77184.

established accurately and that the system is compliant with Sarbanes-Oxley requirements. In light of these major changes, we request that CMS allow at least 180 days after issuance of the Final Rule for manufacturers to implement all reporting changes created by the Proposed Rule.

2. *Use of 12-Month Rolling Average Smoothing Mechanism*

In the Proposed Rule, CMS discussed two possible methodologies for "smoothing" monthly data: (1) 12-month rolling average estimates of all lagged discounts and (2) three-month rolling average estimates of all lagged discounts. CMS has invited comments on the appropriate methodology for calculating monthly AMP.[20] In response to the invitation for comments, we recommend that CMS allow manufacturers the choice of whether or not to use a smoothing mechanism but specify that smoothing must be done, if at all, using an annual period.

We support smoothing with an annual period rather than with a three-month period because the longer time period allows the AMPs to be less volatile. Smoothing has produced positive results in ASP pricing for Medicare Part B drugs, particularly in Healthcare Common Procedure Coding System ("HCPCS") codes that apply to multiple source products. Generic products are particularly well-suited for smoothing, due to the need to account for, in AMP, discontinued products, backordered products, and the large dollar value of chargebacks customarily processed for wholesaler sales for generic products. As a result, generic manufacturers should be encouraged (but not required) to use annual smoothing in the AMP calculation, in order to accommodate transaction timing and minimize fluctuations.

3. *Timeline for Use of Monthly AMPs*

When CMS implemented ASP pricing for Medicare Part B drugs, the agency provided manufacturers with a six- to nine- month "test" period. During this period, manufacturers could gain an understanding of the new requirements and make the necessary system-level adjustments to implement these requirements to ensure accurate reporting. Moreover, CMS guaranteed that it would not use ASP for reimbursement during this "test" period.

Similarly, when CMS began the implementation of the new Medicaid drug pricing requirements of the DRA, the agency recognized the need to allow extra time for manufacturers to come into compliance with the new requirements. While the DRA required publication of AMPs as of July 2006, CMS used its discretion to make these data available at that date only to the States and not to the public. According to then-Administrator Mark McClellan, the agency delayed public disclosure for the following reasons:

> We know that an imprecise definition of AMP, especially if publicly posted, will be misleading to state Medicaid directors and others who will use this as a

[20] 71 *Fed. Reg.* 77186.

> reference point for setting pharmacy reimbursement. . . Consequently, I am announcing today that CMS will not publicly release the current AMP figures. They just aren't the right numbers to use.[21]

In the press release accompanying the publication of the Proposed Rule, CMS indicated its intention to begin making AMP data available to States and to the public in late spring.[22] However, the same concerns expressed by Dr. McClellan in May 2006 still apply, since manufacturers have not been afforded sufficiently clear guidance and sufficient time to operationalize the new requirements to guarantee that AMP submissions will be accurate and consistent by late spring.

For these reasons, we recommend that CMS follow the ASP model when implementing AMP pricing for Medicaid drugs. To this end, as mentioned above, CMS should provide a 180 day period after the Final Rule is published for manufacturers to come into compliance with the new requirements. Further, CMS should indicate that the first reporting period will commence 90 days after the end of this implementation period. Only at the end of this reporting period could State Medicaid agencies rely on AMPs for reimbursement purposes. Finally, in addition, we request that manufacturers be permitted to refile monthly AMPs for up to three years after initially submitted, as is currently allowed with respect to quarterly AMP data.

Such allowances by the agency would not only treat manufacturers fairly in light of the burdensome changes required by the rule, but would also help ensure that data were not used for reimbursement until they were likely to be accurate and consistent across manufacturers. We suggest that CMS make these timing issues clear by publishing a timeline indicating how new monthly AMPs will be used over time.

4. ***Net Unit Reporting***

The government needs a program in place to determine products per manufacturer that are not widely available to the retail class of trade. For ASPs, manufacturers are currently required to submit net units shipped (excluding returns) for each product so CMS will have some assistance in determining if a product is widely available. We recommend that the same method be adopted for AMPs. However, because the net unit number alone does not indicate whether a product is widely available, the government will also need to consider additional factors, such as whether the product is available from several wholesalers. Nonetheless, net unit reporting is a good tool to be used as part of this process of determining widely available products, and it should be required of manufacturers in their AMP submissions. Moreover, the net unit information could also be used for weighting, as required for the rebate calculation process. Importantly, CMS

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[21] Remarks of Mark B. McClellan, MD, PhD, as delivered to the NCPA 38th Legislation and Governance Conference (May 22, 2006).

[22] CMS, "Medicaid Drug Pricing Regulation Proposed" (December 15, 2006), *available at* http://www.cms.hhs.gov/apps/media/press/factsheet.asp?Counter=2062&intNumPerPage=10&checkDate=&checkKey=&srchType=&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date.

must keep in mind that this information is confidential and, therefore, cannot be posted on the agency's website or otherwise released to the public.

5. ***Record-Keeping Requirements***

In the Proposed Rule, CMS proposes the requirement that manufacturers retain "records used in calculating the customary prompt pay discounts and nominal price discounts reported to CMS."[23] To provide adequate guidance to manufacturers concerning implementation of the new record retention requirements, CMS should specify what prompt pay information is needed for retention.

6. ***Reporting Requirements***

In the Proposed Rule, CMS stipulates that customary prompt pay discounts are to be reported as an aggregate dollar amount for each reported NDC-9, so as to include discounts extended to all purchasers in the rebate period.[24] However, the new file formats that have been provided to manufacturers from CMS for quarterly reporting do not include specifications for reporting customary prompt pay aggregate dollars. We ask that CMS include a field for aggregate prompt pay dollar amount in the file used for quarterly price submissions, or that CMS expressly allow manufacturers to submit aggregate prompt pay dollar amounts for each NDC-9 in a separate file with format determined by each manufacturer.

CMS also proposes to require manufacturers to report revisions to customary prompt pay discounts and nominal prices reported to CMS.[25] From this statement alone, it is unclear whether manufacturers need to do this reporting on an accrued basis or on a cash basis (i.e. whether manufacturers must report what they offered to customers or what their customers actually paid). CMS should specify that manufacturers report what they offered to customers, as this is the only information manufacturers are able to report.

7. ***Certification Requirement***

In the Proposed Rule, CMS proposes to add a requirement that manufacturers must certify the pricing reports they submit to CMS. CMS proposes that this certification must be made by "the manufacturer's Chief Executive Officer (CEO), Chief Financial Officer (CFO), or an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO."[26] We recommend that this requirement be altered slightly to allow an individual who reports directly or ***indirectly*** to the CEO or CFO to provide the certification. This flexibility is needed because a company's CEO or CFO (or their direct report) is not always available to review and certify data reports on a monthly basis.

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[23] 71 *Fed. Reg.* 77185.
[24] 71 *Fed. Reg.* 77198.
[25] 71 *Fed. Reg.* 77185.
[26] 71 *Fed. Reg.* 77186.

8. *Negative AMPs*

The Proposed Rule requires manufacturers to report AMPs on a monthly basis, whereas these data were formerly submitted only quarterly. One consequence of the new monthly AMP reporting requirements is a potential increase in the number of negative AMPs. CMS should clarify that negative AMPs should be reported.

Upper Limits for Multiple Source Drugs – Section 447.514

1. *Definition of "Formulation"*

Pursuant to the DRA, the Proposed Rule stipulates that upper limits are to be placed on multiple source drugs when there are two or more therapeutically and pharmaceutically equivalent formulations, regardless of whether all additional formulations are rated as such.[27] For purposes of determining which multiple source drugs require upper limits, the term "formulation" should be clarified to mean products of the same form and route of administration (i.e., tablet to tablet, controlled release tablet to controlled release tablet, liquid to liquid, etc.). It would not be appropriate for a liquid or controlled release tablet to be set at the same level of reimbursement as a standard tablet formulation. Such a comparison is unreasonable as the products will have different prices and be sold separately. We believe this is the intent of the Proposed Rule.

2. *Availability of Generics at the FUL Price*

CMS proposes "additional criteria to ensure that a drug is nationally available at the FUL price and that a very low AMP is not used by us to set a FUL that is lower than the AMP for other therapeutically and pharmaceutically equivalent multiple source drugs."[28] Specifically, CMS proposes to set the FUL based on the lowest AMP that is not less than 30 percent of the next highest AMP for that drug. CMS solicited comments regarding whether 30 percent is an appropriate measure to use.

While we support the intent of the proposed methodology, the 30 percent rule alone does not accomplish the stated objective of preventing outliers from determining the FUL. We are unaware of any evidence or experience, and CMS has offered no data, supporting the theory that products with AMPs that are 29 percent of the next highest AMP should qualify as outliers, but that those with AMPs that are 30 percent of the next highest AMP are routinely and nationally available. However, we believe the 30 percent rule, when used in conjunction with an aggregate, industry-wide weighted average AMP (as discussed below), is a good place to start. Over time, we request that CMS revisit the 30 percent rule to assess whether the accumulated AMP data support setting the threshold at a different percentage. Nonetheless, because there is nothing special about 30 percent, the use of this number alone as a threshold would not guarantee that outliers were removed from the FUL calculation.

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[27] *Id.*

[28] 71 *Fed. Reg.* 77188.

To accomplish this intent of "ensur[ing] that the FUL will be set at an adequate price to ensure that a drug is available for sale nationally," we would recommend using the 30 percent rule in conjunction with an aggregate, industry-wide weighted average AMP.[29] When calculating FULs, CMS should first remove any AMPs less than 30 percent (or whatever threshold is later adopted) of the next highest AMP, and then from this set of AMPs, calculate the aggregate, industry-wide weighted average AMP. This two-step process would ensure that the resulting FUL represents a nationally available price, not an arbitrary number.

3. ***Reporting of AMPs at the NDC Nine-Digit Level***

The currently reported AMP is based on the nine-digit NDC, combining all package sizes of the drug into the same computation. CMS proposed to continue this policy and solicited comments on the alternative approach of using 11-digit NDC to calculate AMP as well as comments on the merits of using both approaches in calculating AMP for the FUL calculation.[30] We do not find a compelling reason to move away from the nine-digit NDC calculation, and we are concerned that significant system changes would be required to support 11-digit reporting. Therefore, we favor the proposed AMP reporting at the nine-digit level for FUL computation as well as rebate purposes.

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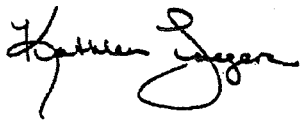
Thank you for the opportunity to submit these comments. GPhA looks forward to working with CMS while these provisions of the Proposed Rule are being finalized. Please do not hesitate to contact us if you have any questions or concerns.

Sincerely,



Kathleen D. Jaeger

[29] 71 *Fed. Reg.* 77187.
[30] *Id.*